II. The Amendment

The amendments herein add no new matter.

New claim 57, 58, 65, 66, 67, 75, 76, 86, 87, 97, and 98 are drawn to disulfide-stabilized Fvs ("dsFvs"), and to constructs and methods employing 3B3(dsFv). DsFvs and 3B3(dsFv) are supported throughout the specification, including claims 6, 15, 28, 36, and 44, as originally presented and page 13, lines 20-32.

New claim 59 to a nucleic acid that encodes a single chain fusion protein tracks claim 12 as originally presented, but recites that the nucleic acid encodes a cytotoxin rather than *Pseudomonas* exotoxin ("PE"), which is a preferred embodiment thereof. Immunotoxins comprising cytotoxins (including cytotoxins other than PE) are supported throughout the specification, including claim 1 as originally presented and page 18, line 27 to page 19, line 23. New claim 60 is supported throughout the specification, including the passage just noted and claim 53 as originally presented. New claims 61-64 are supported throughout the specification and restate original claims 13-16.

New claim 68 is supported throughout the specification, including claim 25 as originally presented. The new claim recites that the claimed immunotoxin comprises a cytotoxin. Support in the specification for immunotoxins comprising cytotoxins other than PE is found throughout the specification, including claim 1 as originally presented and page 18, line 27 to page 19, line 23. New claim 69 recites particular cytotoxins and is supported by the passage just cited and by claim 53 as originally presented. New claims 70-74 are supported by claims 26-30 as originally presented. New claims 77 and 78 are supported by claims 31 and 32 as originally presented.

Claim 79 is supported throughout the specification, including claim 33 as originally presented. The new claim recites that the claimed immunotoxin comprises a cytotoxin. Support in the specification for immunotoxins comprising cytotoxins other than PE is found throughout the specification, including claim 1 as originally presented and page 18, line 27 to page 19, line 23. New claim 80 recites particular cytotoxins and is supported by the passage just cited and by claim 53 as originally presented. Claims 81-

85 are supported by, e.g., claims 34-38 as originally presented. Claims 88 and 89 are supported by, for example, claims 39 and 40 as originally presented.

New claim 90 is supported throughout the specification, including claim 41 as originally presented. The new claim recites that the claimed immunotoxin comprises a cytotoxin. Support in the specification for immunotoxins comprising cytotoxins other than PE is found throughout the specification, including claim 1 as originally presented and page 18, line 27 to page 19, line 23. New claim 91 recites particular cytotoxins and is supported by the passage just cited and by claim 53 as originally presented. Claims 92-96 are supported by, e.g., claims 42-46 as originally presented. Claims 99-103 are supported by, for example, claims 47-51 as originally presented.

Applicants state for the record that the claims added herein are not intended to narrow the scope of the corresponding claims which they replace and the amendments herein are not made to overcome prior art. Accordingly, Applicants maintain they are entitled to the full range of equivalents for the claims.

III. The Office Action and Response Thereto

The Action divides the claims into 5 groups. According to the Action, the groups "do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding technical feature." Action, at page 2. The Action then states that 37 C.F.R. §1.475(d) provides that "where multiple products and processes are claimed, the main invention shall consist of the first invention of the category first mentioned in the claims." Action, at page 2. The Action asserts that "the main invention (Group I) comprises the first-recited product, linear peptides [sic]". The Action further contends that the "ISA/US considers that any feature which the subsequently recited products and methods share with the main invention does not constitute a special technical feature within the meaning of PCT Rule 13.2 and that each of such products and methods accordingly defines a separate invention." Action, at pages 2-3, bridging sentence.

1. The Action Misconstrues the Rules. Properly Read, The Rules Support Examining the Claims Together

A. PCT Rule 13.2 Supports Examining the Claims Together

The Action misconstrues 37 C.F.R. § 1.475 and PCT Rule 13.2 to arrive at an incorrect result. Correctly read, the "separate" inventions found by the Action share the same technical feature and share unity of invention. Thus, as explained below, the groups should not have been separated and should be examined together.

The Action asserts, but does not show, that the groups of inventions it finds present in the claims do not share the same special technical feature under PCT Rule 13.2. But, the Action does not define what a special technical feature is or analyze the invention to determine whether or not a special technical feature of Rule 13.2 is present. Rule 13.2 defines special technical features to "mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." *See*, PCT Rule 13.2 (for the Examiner's convenience, Applicants note the Rule can be found at MPEP page T-48 of the 8th Edition).

The claims in the present application share at a minimum the special technical feature of scFv antibodies targeted to cells on which gp120 is present. The immunotoxins use the antibodies, the claimed methods use the immunotoxins, the nucleic acids encode the immunotoxins, and the compositions comprise the immunotoxins. Thus, the claims all exploit and are linked by the same technical feature.

The Applicants' reading of PCT Rule 13.2 is confirmed by the European Patent Office ("EPO"), acting as the International Search Authority with respect to the parent PCT application of which the present application is a national stage filing under 35 U.S.C. § 371. The EPO examiner examined together all of the claims of the parent PCT application. Since the EPO routinely applies unity of invention rules to applications before it, its examiners tend to have considerable experience in the application of those rules. The present Action provides no analysis or explanation why the EPO examiner, experienced in the application of unity of invention principles in general and of PCT Rule

13.2 in particular, erred in examining all the claims together while the Action is correct in finding that, under the same Rule, the claims can be divided into groups. Applicants submit that no such analysis can be made, because the EPO decision as the ISA reflects the correct application of PCT Rule 13.2.

B. Rule 1.475 Does Not Require Separation of the Groups

As noted above, the Action does not refer to the definition of what constitutes a special technical feature, and does not analyze whether the claims share the same technical feature. The Action simply dismisses the immunotoxins of the first claims (which are chimeric molecules comprising a targeting portion and a cytotoxin) as "linear peptides." The Action maintains that the rules, and particularly Rule 1.475, support separating the groups present in the application under examination. The Action's analysis is that the various types of claims presented in this case are "multiple products and processes" which are to be separated under Rule 1.475(d). It appears that the Action rests on the syllogism that claims containing more than one type of invention constitute multiple inventions, that multiple inventions trigger Rule 1.475(d), and that the multiple inventions are thus properly separated under the rule. This syllogism is not correct.

As an initial matter, the requirements of Rule 1.475 are not different than those set forth in PCT Rule 13.2. MPEP § 1893.03(d) states that §1.475 was amended in 1993 to correspond to PCT Rule 13.2. Each of the discussions of Rule 1.475 and of PCT Rule 13.2 in the MPEP supports the examination of the present claims in the same application.

The Examiner's attention is first drawn to MPEP § 1850.[1] MPEP § 1850 states "Any international application must relate to one invention only or to a group of inventions so linked as to form a single general inventive concept." (Emphasis added.) Thus, it is clear that claims can constitute a group of inventions and still properly be

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[1] While § 1850 directly concerns consideration of unity of invention before the ISA, the section states it is also relevant to considering the same issues in the national stage under 35 U.S.C. § 371.

examined in a single application under Rule 1.475 so long as the claims form a single inventive concept.

MPEP § 1850 further states that, when the Office considers applications during the national stage under § 371 (such as the application under examination here), unity of invention practice under PCT Rule 13.2 will be followed and that, in applying PCT Rule 13.2 to national stage applications, "examiners should consider for unity of invention all the claims to different categories of invention in the application and permit retention in the same application for searching and/or preliminary examination, claims to the categories which meet the requirements of PCT Rule 13.2" (MPEP § 1850, page 1800-61. Emphasis added). Thus, claims in different categories of inventions should be examined together so long as they meet, as in this case, the requirements of PCT Rule 13.2.

This point is further confirmed by MPEP § 1893.03(d), which discusses the unity of invention requirement during the national stage. The section states that applicants are entitled to have examined in a single application those inventions which are so linked as to form a single inventive concept. The section states that whether or not inventions are so linked as to form a single inventive concept is determined on the basis of whether there is at least one common or corresponding technical feature, which (tracking PCT Rule 13.2) is defined to mean those features "which each claimed invention, considered as a whole, makes over the prior art." MPEP § 1893.03(d), at page 1800-149.

Thus, the MPEP confirms that claims that share the same special technical feature are to be examined together in national stage applications under § 371, without regard to normal restriction practice. As noted earlier, the claims at issue share, at a minimum, the special technical feature of antibodies that bind to HIV gp120 with the binding specificity and minimum affinity of antibody 3B3. All of the groups of claims are therefore linked so as to form a single inventive concept. Accordingly, the claims should be examined together in the present application.

Applicants again respectfully note that their interpretation of the claims is supported by the fact that the EPO, operating as the ISA and applying the same PCT Rule 13.2, examined together all the claims in this application. In contrast, the Action provides no explanation why its application of Rule 13.2 diverges from that of the EPO.

C. Summary

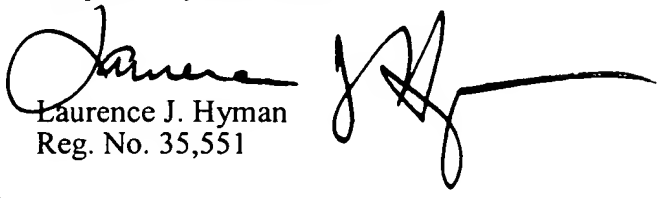
In sum, the claims in this application share the same special technical feature and are so linked as to form a single general inventive concept. The finding to the contrary in the Action is unsupported and is contrary to the conclusion reached by the EPO in applying the same rule to the same claims. The restriction imposed by the Action should be reconsidered and, upon reconsideration, should be withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, he is invited to telephone the undersigned at 415-576-0200.

Respectfully submitted,



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